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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/721,131
Filing Date: November 22, 2000
Appellant(s): BASS, RALPH L.

Jennifer L. Skord
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed June 28, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is deficient for the following reasons: (1) the summary of the invention should indicate that "alleviation of the HIV infection" means reduction of HIV infection with the end or desired result being testing negative for the presence of HIV infection (Specification, pg. 11, lines 18-23); (2) the summary of the invention should indicate that Claim 28 recites "contains up to 20"%" as opposed to simply "containing".

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows:

Issue 1: Appellant's statement of the issue implies that the rejection of claims 22-42 for lack of credible utility and enablement was based solely on the presence of prophetic examples. To the contrary, said rejection is based on the totality of the evidence including the status of HIV treatment up to and including the filing date of the present Application, evidence relative to inoperability of Appellant's claimed invention and Appellant's disclosure, including the lack of working examples.

Issue 2: Appellant's statement of the issue implies that the rejection of claim 35 for lack of enablement was based solely on the presence of prophetic examples. To the contrary, said rejection is based on the totality of the evidence including the status of transdermal administration up to and including the filing date of the present Application, evidence relative to enablement of Appellant's claimed invention and Appellant's disclosure, including the lack of working examples.

Issue 3: Appellant's statement of the issue states that recent research studies report a correlation between the presence of nutrient deficiency for each of the nutrients in claim 28 and a decrease in the ability to inhibit HIV is contradicted by the research studies themselves and Appellant's statement in the Argument section that the research studies do not address the nutrients, sodium chloride and potassium or iodine (Appeal Brief (6/28/2004), Pg. 11). Further, Appellant's statement of the issues implies that Claim 28 requires the presence of sulfur, phosphorus, zinc, manganese, iron, copper, chromium, iodine, magnesium, cobalt, selenium or combinations thereof. However, Claim 28 recites "up to 20"% by weight of another ingredient selected from the group consisting of S, P, Zn, Mn, Fe, Cu, Cr, I, Mg, Co, Se, and combinations thereof", as such, Claim 28, as claimed, can include 0% by weight of said ingredients.

(7) Grouping of Claims

Appellant's brief includes a statement that claim 28 does not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,661,023 HRINDA et al. 8-1997

Cecil Textbook of Medicine, Vol. 2 (21st Ed. , 2000), pp. 1889, 1904-1907, 1933-1945.

Drug Facts and Comparisons (54th Ed. 2000), pp. 46, 116,117.

Martindale, The Extra Pharmacopoeia (30th ed., 1993), pp. 851-863, 1033, 1034.

STN/CAS online, file PROMT, Acc. No. 96:637898 (Zabel, ed., "Salt water soaking possible alternative psoriasis treatment now available in Germany", Dermatology Times (Nov. 1996), pp. S20), Full Text.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 22-42 are rejected under 35 U.S.C. 101 for lack of credible utility and for lack of enablement under 35 USC 112, first paragraph.

Claim 35 is rejected for lack of enablement of transdermal administration of the claimed amounts of sodium chloride in the upper GI tract.

These rejections are set forth in a prior Office Action, mailed on June 18, 2003.

(11) Response to Argument

Claims 22-42 are rejected under 35 U.S.C. 101 for lack of credible utility and for lack of enablement under 35 USC 112, first paragraph.

Contrary to Appellant's assertions, Examiner has not ignored the premise that there is no legal requirement for actual working examples or that the inventor set forth correctly, or even to know how or why the invention works. Further, Examiner does not dispute the fact that Appellant's Specification provides a written description of a method for administration of sodium chloride and that the Specification alleges that administration of sodium chloride will alleviate HIV infection. However, the written description requirement is separate and distinct from the enablement requirement. In re Barker, 194 USPQ 470 (CCPA 1977; Vas-Cath, Inc. v. Mahurkar, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991). Further, although there is no legal requirement for actual working examples, when a patent Appellant chooses to forego exemplification and bases utility on broad terminology and general allegations, he runs the risk that unless one with ordinary skill in the art would accept the allegations as obviously valid and correct, the examiner may, properly, ask for evidence to substantiate them. See Ex parte Sudilovsky, 21 USPQ2d 1702, 1705 (BdPatApp&Int 1991). Furthermore, unlike the present case, the "prophetic" examples in Atlas Powder Co. v. E.I. Du Pont De Nemours Co.224 USPQ 409, 414 (Fed. Cir. 1984) were based on actual experiments which were slightly modified in the patent to reflect what the inventor believed to be optimum.

In any case, the issue in the present rejection is not that Appellant has failed to describe the claimed invention but that the utility described in the Specification is not credible. Since Appellant's claimed invention lacks credible utility, the claims are also rejected under 35 USC 112, first paragraph, because a person skilled in the art cannot practice the invention. See In re

Swartz, 56 USPQ2d 1703,1703,1704 (CAFC 2000); see also Newman v. Quigg, 11 USPQ2d 1340, 1345 (CAFC 1989) (cited by In re Cortright, 49 USPQ2d 1464, 1469 (Fed. Cir. 1999)) (the Court held that because the method did not produce the claimed result, following the teachings of the specification, the claimed invention was unpatentable under 35 U.S.C 101, for lack of utility, and 35 USC 112, first paragraph, for lack of enablement).

Appellant attempts to distinguish Hrinda et al. (US Pat. 5,661,023), which provides evidence as to the inoperability of Appellant's claimed invention, by arguing, based in part on the Merck brochure entitled "Livin'It", attached hereto as Exhibit A, that one of ordinary skill in the art would conclude that HIV attached to a CD4 T-cell in the human body would act differently from free HIV in phosphate buffered saline. The Merck brochure entitled "Livin'It" discloses the use of an organic drug CRIXIVAN® for the treatment of HIV. The Merck brochure does not[1] provide evidence that administration of sodium chloride as claimed would be effective in alleviating HIV infection or otherwise show that sodium chloride would act to disrupt the smaller HIV. As such, the Merck brochure does not provide evidence from which one of ordinary skill in the art could conclude that HIV attached to a CD4 T-cell in the human body would act differently from free HIV in phosphate buffered saline.

Appellant also argues that one of ordinary skill in the art would recognize that phosphate buffered saline solution is not coursing through the veins and arteries of the human and further asserts, without evidence, that HIV are not free floating in the human body. The Merck brochure discloses that once in the blood stream HIV attaches itself to the human CD4 T-cell. As such, it

[1] As Appellant has noted, the prior Office Actions contained a typographical error with the following statement being what was intended: "Further as set forth in the prior Office Action, Merck brochure does **not** [*sic*] appear to show administration of sodium chloride as claimed would be effective in alleviating HIV infection or otherwise show that sodium chloride would act to disrupt the smaller HIV virus cells" (emphasis added).

appears that HIV is free floating prior to attachment to said cell. Further, Appellant has not provided any evidence, that knowing that phosphate buffered saline is not coursing through the blood stream, that one of ordinary skill in the art would conclude that Hringa et al. does not provide evidence of inoperability of the claimed invention. The arguments of counsel alone cannot take the place of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure. See In re Budnick, 190 USPQ 422, 424 (CCPA 1976); In re Schulze, 145 USPQ 716,718 (CCPA 1965)(argument in the brief does not take place of evidence in the record); In re Cole, 140 USPQ 230 (CCPA 1964). For example, in a case where the record consisted substantially of arguments and opinions of Appellant's attorney, the court indicated that factual affidavits could have provided important evidence on the issue of enablement. See In re Knowlton, 183 USPQ 33, 37 n 4 (CCPA 1974). As such, said assertions do not provide evidence from which one of ordinary skill in the art could conclude that HIV attached to a CD4 T-cell in the human body would act differently from free HIV in phosphate buffered saline.

Appellant, argues in the alternative, that since Hrinda et al. shows that phosphate buffered saline removed the HIV from the resin column that one of ordinary skill in the art would expect HIV particles attached to human CD4 T-cells would similarly be removed. However, as indicated by Appellant, Hringa et al. discloses that HIV particles attached to the resin are washed with an aqueous solution containing 0.1-0.55 M sodium chloride with elution off the resin requiring a higher sodium chloride concentration of 0.6-2 M (Appeal Brief (6/28/2004). According to Appellant's Specification, the administration of sodium chloride as claimed should result in circulating levels of NaCl within the range of about 0.05 to about 1.0 μM (Specification, pg. 12, lines 10-12) which is far below the levels disclosed in Hringa et al. to be useful for

washing HIV without removing the same from the resin. As such, Hringa et al., even under this alternative theory, supports the conclusion that Appellant's claimed invention lacks credible utility.

Appellant argues that because Appellant's claimed invention does not claim the above theory, that there is no need for working examples, or anything else, for appellant to prove how his invention works. However, this not the issue. The issue is that Appellant has not shown that the claimed invention works at all. Appellant's reliance on In re Cortright is misplaced. Unlike the present Specification, the written description in In re Cortright provided actual results showing hair growth. In re Cortright, 49 USPQ2d 1464,1465,1467 (CAFC 1999). Appellant provides no evidence "that Cortright's working examples were for her other claim which issued in her U.S. Patent No. 6,033,676, not for rejected claim 15" (Appeal Brief (6/28/2004), pg. 10). As indicated in the Cortright opinion, claim 1 recited a method of "treating scalp baldness" by applying the active ingredient and claim 15 recited applying the same active ingredient "to cause hair to grow again on the scalp." *Id.* at . 1465. Further, the opinion in discussing claim 15 indicated that Cortright was not required to prove the cause of the resultant hair growth. *Id.* at pg.1469. See also US Pat. 6,033,676, Column 1, lines 40-47, Column 2, lines 7-55. As such, the working examples applied to both claims.

In response to the assertion that administration of sodium chloride to alleviate HIV infection is inherently suspect, Appellant argues that treating HIV infection was once considered an inherently unbelievable undertaking. Appellant does not provide any evidence supporting this argument. Appellant also argues, based on In re Cortright, that baldness, once considered an inherently unbelieveably undertaking, has gained acceptance. However, Appellant has made no

showing that the effectiveness of AZT and 3TC in treating HIV infection or the effectiveness of various hair growth treatments establishes that the claimed invention is not inherently suspect or has credible utility. See e.g. Ex parte Balzarini, 21 USPQ2d 1892, 1894-1897 (BdPatApp&Int 1991); Newman v. Quigg, 11 USPQ2d 1340, 1345 (CAFC 1989).

There is no basis for Appellant's assertion that patent applications directed to new medical use of a known composition, where the patent application has prophetic examples, are not deemed by the USPTO to be *per se* inherently suspect. The PTO may establish a reason to doubt an invention's asserted utility when the written description "suggest[s] an inherently unbelievable undertaking or involve[s] implausible scientific principles." In re Cortright at 1466 (citing to In re Brana, 34 USPQ2d 1436, 1441 (Fed Cir. 1995). In this case, at the time the application was filed, the generally accepted goal of anti-HIV therapy was to ideally completely inhibit HIV replication through the use of reverse transcriptase inhibitors and protease inhibitors (Cecil Textbook of Medicine, Vol. 2 (21st Ed. 2000), pp. 1933,1934). As such, the administration of sodium chloride to alleviate HIV infection appears to be inherently suspect.

In a prior Appeal Brief (4/25/2003), Appellant submitted 38 research studies, however, none address the use of sodium chloride in alleviating HIV infection or the effects of sodium chloride on HIV. Appellant has withdrawn references 1-6, 10-19 as being published after the November 22, 2000 filing date of the application in accordance with In re Glass, 181 USPQ 31 (CCPA 1974) and Curtis-Wright Corporation et al. v. Link Aviation, Inc., 124 USPQ 266, 285 (DC NNY 1959). Although Appellant indicates that references 8, 12, 30 and 31 were withdrawn, Appellant states that references 7-9 and 20-38, which apparently include references

8, 30 and 31, remain (Appeal Brief (6/28/2004), pg. 11). A copy of the research studies submitted by Appellant, with references 1-6, 10-19 redacted, is attached hereto as Exhibit B.

Appellant argues that the remaining research studies 7-9, 20-38 have reported a correlation between a decrease in the ability of HIV-infected persons to inhibit HIV and the presence in HIV infected persons of a deficiency for various nutrients, such as sulfur, phosphorous, zinc, manganese, iron, chromium, magnesium, cobalt and selenium. Examiner, however, notes that none of the claims require the presence of sulfur, phosphorous, zinc manganese, iron, copper, chromium, iodine, magnesium, cobalt and/or selenium. Claim 28 recites the phrase "up to about 20%" which includes 0%. See In re Mochel, 176 USPQ 194,195 (CCPA 1972) (the phrase "up to" includes zero as the lower limit). Appellant notes that references 8, 21, 30 and 31 have descriptors, however, nothing in said references establishes a correlation between a decrease in the ability of HIV-infected persons to inhibit HIV and the presence in HIV infected persons of a deficiency for various nutrients or that supplementation of said nutrients will alleviate HIV infection. Although Appellant's claimed invention requires sodium chloride and may include potassium and/or iodine, Appellant admits that the research studies do not address sodium chloride, potassium or iodine (Appeal Brief (6/28/2004), pg. 11). Further, there are deficiencies with the other references:

7. (2000) Droege et al. does not disclose a causal correlation between sulfur deficiency and alleviation of HIV infection nor does it disclose that administration of sulfur will alleviate HIV infection. In fact, it is disclosed that N-acetyl-cysteine was administered and that the effect on viral load was not consistent and may warrant further study and that impairment of immunological functions in HIV patients results at least partly from cysteine deficiency. See also research study no. 25 which discloses that administration of N-acetyl-cysteine did not alter viral load.

9. (1999) Discloses that out of manganese, iron, copper, chromium, cobalt, selenium and zinc, only zinc exhibited a reverse transcriptase activity in vitro in a dose-response fashion. However, see research study nos. 32 and 35 which disclose that zinc supplementation was

associated with poorer survival of HIV infected patients and progression to AIDS, respectfully, and research study no. 27 which discloses that there was no statistically significant difference in zinc or selenium levels amongst HIV infected and uninfected children.

20. (2000) Droege et al. does not disclose a causal correlation between sulfur deficiency and alleviation of HIV infection nor does it disclose that administration of sulfur will alleviate HIV infection. In fact, it is disclosed that N-acetyl-cysteine was administered and that the effect on viral load was not consistent and may warrant further study and that impairment of immunological functions in HIV patients results at least partly from cysteine deficiency. See also research study no. 25 which discloses that administration of N-acetyl-cysteine did not alter viral load.

22. (2000) Does not disclose a causal correlation between zinc or iron deficiency or supplementation and alleviation of HIV infection. See research study nos. 32 and 35 which disclose that zinc supplementation was associated with poorer survival of HIV infected patients and progression to AIDS, respectfully, and research study no. 27 which discloses that there was no statistically significant difference in zinc or selenium levels amongst HIV infected and uninfected children.

23. (1999) Does not disclose a causal correlation between zinc deficiency or supplementation and alleviation of HIV infection. See research study nos. 32 and 35 which disclose that zinc supplementation was associated with poorer survival of HIV infected patients and progression to AIDS, respectfully

24. (1999) Does not disclose a causal correlation between any of the claimed nutrients and alleviation of HIV infection and in fact does not mention the claimed nutrients at all.

25. (1998) Does not disclose a causal correlation between sulfur or selenium deficiency and alleviation of HIV infection and in fact discloses that administration of N-acetylcysteine and sodium selenite did not affect viral load.

26. (1998) Does not disclose a causal correlation between selenium deficiency or supplementation and alleviation of HIV infection. See research study no. 25 which discloses that administration of sodium selenite did not alter viral load, research study no. 9 which discloses that selenium does not decrease reverse transcriptase in a dose-response fashion and research study no. 27 which discloses that there was no statistically significant difference in zinc or selenium levels amongst HIV infected and uninfected children.

27. (1997) Does not disclose a causal correlation between zinc or selenium deficiency and alleviation of HIV infection and in fact discloses that there was no statistically significant difference in zinc or selenium levels amongst HIV infected and uninfected children.

28. (1997) Does not disclose a causal correlation between magnesium deficiency or supplementation and alleviation of HIV infection.

29. (1997) Does not disclose a causal correlation between supplementation of selenium and alleviation of HIV infection. See research study no. 25 which discloses that administration of sodium selenite did not alter viral load, research study no. 9 which discloses that selenium does not decrease reverse transcriptase in a dose-response fashion and research study no. 27 which discloses that there was no statistically significant difference in zinc or selenium levels amongst HIV infected and uninfected children.

32. (1996) Does not disclose a causal correlation between zinc deficiency and alleviation of HIV infection and in fact discloses that any intake of zinc supplements was associated with poorer survival of HIV infected patients.

33. (1994) Does not disclose a causal correlation between chromium or phosphorus deficiency or supplementation and alleviation of HIV infection.

34. (1996) Does not disclose a causal correlation between zinc deficiency and alleviation of HIV infection and in fact discloses that intake of zinc supplements was associated progression to AIDS.

35. (1993) Discloses that HIV protease is inhibited in vitro by zinc ions at neutral pH but does not disclose a causal correlation between zinc deficiency and alleviation of HIV infection. Further, see research study nos. 32 and 35 which disclose that zinc supplementation was associated with poorer survival of HIV infected patients and progression to AIDS, respectfully, and research study no. 27 which discloses that there was no statistically significant difference in zinc or selenium levels amongst HIV infected and uninfected children.

36. (1993) Does not disclose a causal correlation between selenium deficiency and alleviation of HIV infection and in fact discloses that seroconvertors and nonseroconvertors did not differ in preseroconversion levels of selenium.

37. (1990) Does not disclose a causal correlation between zinc deficiency or supplementation and alleviation of HIV infection. See research study nos. 32 and 35 which disclose that zinc supplementation was associated with poorer survival of HIV infected patients and progression to AIDS, respectfully, and research study no. 27 which discloses that there was no statistically significant difference in zinc or selenium levels amongst HIV infected and uninfected children.

38. (1991) Graham et al. Does not disclose a causal correlation between dietary copper or zinc and alleviation of HIV infection and in fact discloses that dietary levels copper and zinc were not associated with HIV-1 seropositivity or progression to AIDS and that serum copper levels were higher in HIV –1 seropositive progressors. Further, see research study nos. 32 and 35 which disclose that zinc supplementation was associated with poorer survival of HIV infected patients and progression to AIDS, respectfully, and research study no. 27 which discloses that there was no statistically significant difference in zinc or selenium levels amongst HIV infected and uninfected children.

In summary, the references fail to support the conclusion that one of ordinary skill in the art would conclude that the claims 22-42 had credible utility as none of the references disclose the use of sodium chloride to inhibit HIV or alleviate HIV infection. Appellant argues that one of ordinary skill in the art would know that sodium chloride is a nutrient and so are potassium, sulfur, phosphorus, zinc, manganese, iron, copper, chromium, iodine, magnesium, cobalt and selenium. However, as admitted by Appellant, none of the references discuss sodium chloride,

potassium or iodine. Further, as indicated above, none of the research studies provide evidence that dietary supplementation of the other nutrients will alleviate HIV infection. To the extent Appellant is arguing that similarity in structure supports a conclusion that sodium chloride would be effective in alleviating HIV, Appellant has not provided any evidence of the same. See In re Langer, 183 USPQ 288,299 (CCPA 1974) (genus claim was properly rejected for lack of utility even though member of said genus had utility where there was no evidence of functional equivalency). As such, one of ordinary skill in the art would not conclude that credible utility exists for the claimed invention. See e.g. In re Swartz, 56 USPQ2d 1703, 1704 (CAFC 2000).

Appellant attempts to distinguish Sudilovsky by arguing that the Specification provides detailed prophetic examples of the claimed method. Contrary to Appellant's assertions, the specification in Sudilovsky was highly detailed. Ex parte Sudilovsky, 21 USPQ2d at 1705. There is nothing in the Board's opinion that indicates that the Specification in Sudilovsky did not set forth amounts or frequency of the ACE inhibitor to administered to a person. The holding in Sudilovsky turns on the fact that the evidence provided was insufficient to show that the ACE inhibitors where effective against tardive dyskinesia. *Id.* Similarly, in this case, Appellant has provided prophetic examples, which regardless of their detail, are just that, "prophetic", and, thus amount to nothing more than general allegations or suggestions. Although the lack of working examples or experimental evidence is not controlling, the same are factors to be considered in this case which involves "both physiological activity and an undeveloped art". *Id.*

Dependent claim 28 is not separately patentable

Appellant appears to make similar arguments in support of the separate patentability of claim 28 as set forth above. As such, Examiner incorporates the arguments set forth above

herein. Specifically, as indicated above, the rulings in Atlas Powder Co. v. E..I Du Pont De Nemours & Co. and In re Cortright do not conflict with a finding of lack of credible utility. As indicated above, Appellant has not provided evidence from which one of ordinary skill in the art would conclude that HIV in the body would act differently from HIV in phosphate buffered saline, as such, Hrinda et al. supports the conclusion that Appellant's claimed invention lacks credible utility. As indicated above, Appellant's argument that the research studies submitted by Appellant support the conclusion that there is a correlation between a decrease in the ability to inhibit HIV and the presence of HIV-infected person of nutrient deficiency for many of the nutrients recited in claim 28 is without merit. Further, as indicated above, in view of In re Mochel, *supra*, claim 28 does not require the presence of sulfur, phosphorous, zinc, manganese, iron, copper, chromium, iodine, magnesium, cobalt and/or selenium. Furthermore, as indicated above, Appellant admits that the research studies do not discuss sodium chloride and potassium or iodine, as such, the utility rejection may be maintained on this basis alone. See in re Buting, 163 USPQ 689, 691 (CCPA 1969) (citing to In re Harwood, 156 USPQ 673 (CCPA 1968) (utility rejection was maintained as appellant neither limited his claims to the area where utility had not been properly challenged nor submitted evidence refuting that challenge).

Appellant cites specifically to Droege et al. (2000) (research studies nos. 7, 20) and Graham et al. (1991) (research study no. 38) and then invites the Examiner and Board to browse through all of the research studies. Contrary to Appellant's argument, Droege et al. does not show that administration of the element sulfur as claimed by Appellant alleviates HIV infection. Droege et al. discloses administration of N-acetyl-cysteine and indicates that the effect of N-acetyl-cysteine on viral load is not consistent and may warrant further studies. See Ex parte

Busse, et al., 1 USPQ2d 1908, 1909 (BdPatApp&Int 1986) (evidence warranting further study is not equivalent to evidence showing the type of utility required by 35 USC 101); See also research study no. 25 which discloses that administration of N-acetyl-cysteine did not alter viral load. Contrary to Appellant's argument, Graham et al. does not show that many HIV-infected persons had zinc and copper deficiencies or that supplementation of zinc or copper resulted in alleviation of HIV and, in fact, discloses that dietary levels copper and zinc were not associated with HIV-1 seropositivity or progression to AIDS and that serum copper levels were higher in HIV –1 seropositive progressors. See research study nos. 32 and 35 which disclose that zinc supplementation was associated with poorer survival of HIV infected patients and progression to AIDS, respectfully, and research study no. 27 which discloses that there was no statistically significant difference in zinc or selenium levels amongst HIV infected and uninfected children. Appellant's invitation to browse through all the research studies is insufficient to establish that said research studies provide objective evidence of utility. See e.g. In re Swartz, 56 USPQ2d 1703, 1704 (CAFC 2000).

Since Appellant has not provided evidence of functional equivalency and the research studies do not support a conclusion that each of the nutrients in claim 28 have credible utility relative to alleviation of HIV infection, the utility rejection may properly be maintained as to claim 28. As such, claim 28 is not separately patentable.

Claim 35 is rejected for lack of enablement of transdermal administration of the claimed amounts of sodium chloride in the upper GI tract

Appellant argues that Examiner appears not to understand transdermal administration versus topical administration and that enablement is provided by reference to US Pat. 5,016,652

in Appellant's Specification. However, Appellant's Specification and US Pat. 5,016,652 clearly make a distinction between transdermal administration for application to the skin and oral administration (Specification, pg. 5, lines 6-15; US Pat. 5,016,652, Columns 1,2, Column 3, lines 1-39). Appellant admits that the Dermatology Times reference discloses that no transdermal uptake of sodium chloride occurs as a result of topical administration of sodium chloride (Appeal Brief (6/28/2004), Pg. 14). Appellant, however, provides no evidence that transdermal administration will deliver the claimed amounts of sodium chloride. US Pat. 5,016,652 does not disclose the administration, transdermal or otherwise, of sodium chloride in the amounts claimed. Further the specification does not[2] appear to show how a skilled artisan would administer sodium chloride in the upper GI tract transdermally when there is no skin in the upper GI tract. As indicated above, transdermal adminstration is through the skin and Appellant has provided no evidence that sodium chloride can be transdermally administered through the skin. As such, Appellant's unsupported argument that something transdermally administered would reach the upper GI tract does not support the conclusion that sodium chloride can be transdermally administered in the upper GI tract. As indicated above, the arguments of counsel do not constitute evidence. Therefore, Appellant has not provided evidence that transdermal administration of sodium chloride in the upper GI tract is enabled.

For the above reasons, it is believed that the rejections should be sustained.

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[2] As Appellant has noted, the prior Office Actions contained a typographical error with the following statement being what was intended: "The specification does **not** [*sic*] appear to show how a skilled artisan would administer sodium chloride in the upper GI tract transdermally when there is no skin in the upper GI tract"(emphasis added).

Respectfully submitted,

Frank Choi
September 7, 2004

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